NOV 2 7 2000

Attachment IV
Proposed 510(k) Summary Statement
(K001521)

Submited by:

Integrated Biosensing Technologies
234 Marshall Street Ste#4
Redwood City CA 94063-1550
Phone: (650) 299-9676

Contact Person:
Babak A. Taheri, Ph.D. ,President

Date Summary was prepared:
May 11, 2000

Name of Device:
Softsens™ - IBT-1XRP

Identification of Substantial Equivalent Device

Device Classification Name	ELECTRODE, CUTANEOUS
Regulation Number	882.1320
510(k) Number	K942921
Device Name	NEUROLINK EEG/EP/EMG SURFACE ELECTRODES

Statement of Intended Use

A cutaneous electrode that is applied directly to a patient's skin to record EEG, EP, EMG or Biofeedback signals.

(revised 082400)

Description of Proposed Device

A stainless steel (300/400 series) disc, typically 10mm (0.39 in.) in diameter. Bottom is flat with the top having a button snap. In use a snap on cable will be connected to the top of the electrode.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 7 2000

Integrated Biosensing Technologies
C/O Mr. Ronald Luich
RJL Associates, LLC
86 Boston Post Road
Waterford, Connecticut 06385

Re: K001521
Trade Name: Softsens™ Electrodes
Regulatory Class: II
Product Code: GXY
Dated: August 24, 2000
Received: August 29, 2000

Dear Mr. Luich:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhan

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 12 – Intended Use Statement

510(k) Number : K001521

Device Name: Softsens™ Electrodes

Indications For Use:

The Softsens™ electrode is a cutaneous electrode that is applied directly to a patient's skin to record EEG, EP, EMG or Biofeedback signals.

(revised11/27/00)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____
(Per 21 CFR 801.109)

OR

Over-The Counter Use_____

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K001521